REMARKS

Claims 1-42 are pending in the present application.

Applicants would like to thank Examiner Baum for the helpful suggestions to address and overcome the objection to the specification; the rejection of Claims 4-8, 34, and 35 under 35 U.S.C. §112, second paragraph; and for the indication that SEQ ID NO:1 and 2 are free of the prior art. Reconsideration is respectfully requested in view of the following comments and the amendments presented herein.

The rejection of Claims 1-22 and 32-35 under 35 U.S.C. § 101 is traversed.

Applicants submit that the present invention provides, in part, nucleotide sequences for the sos2 gene, amino acid sequence for the SOS2 protein, methods of making the SOS2 protein, methods of making a transgenic plant comprising introducing the polynucleotide encoding the sos2 gene, methods of screening for polynucleotides which encode a protein having serine/threonine kinase activity, and a method of increasing salt tolerance in a plant in need thereof (pages 4-5).

MPEP §2107.02 states:

> An applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. 101 and 35 U.S.C. 112; additional statements of utility, even if not "credible," do not render the claimed invention lacking in utility. See, e.g., *Raytheon v. Roper*, 724 F.2d 951, 958, 220 USPQ 592, 598 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984).

When this standard is applied, Applicants submit that the present application is in full compliance with the 35 U.S.C. §101. In particular, Applicants submit that as it should be readily apparent that each of the objects highlighted above would individually satisfy the "need only make one credible assertion" test.

MPEP §2107.02 further states:

> An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. ...
>
> To properly reject a claimed invention under 35 U.S.C. 101, the Office must (A) make a *prima facie* showing that the claimed invention lacks utility, and (B) provide a sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing. *In re Gaubert*, 524 F.2d 1222, 1224, 187 USPQ 664, 666 (CCPA 1975)

Applicants submit that the Examiner has, in no way, provided even a shred of evidence to support a prima facie showing that the claimed invention lacks utility. In particular, the Examiner has failed to provide a "sufficient evidentiary basis" or even attempt to "make a prima facie showing that the claimed invention lacks utility" for each and every asserted utility noted above.

In an effort to provide some rationale for this ground of rejection, the Examiner chooses to focus on the serine/threonine kinase activity of the SOS2 protein and the underlying mechanism behind its role in salt tolerance. The Examiner even goes so far as to state that "without knowing the pathway of which process Applicant's SEQ ID NO:1 is involved in, and how SEQ ID NO:1 can be used to achieve a particular result, it is unclear how one skilled in the art would use the claimed invention." (paper number 10, page 6, lines 4-7). However, there is not now, nor ever has been, a requirement for Applicant to disclose or even be in possession of an unequivocal underlying mechanism for the utility asserted.

In fact, Applicants have provide an extensive explanation of the primary problem to be solved, as well as the role the claimed invention plays in solving this problem. In particular, Applicants note that external Na^+ causes K^+ deficiency by inhibiting K^+ uptake into plant cells (page 2, lines 27-28). Na^+ accumulation within the cell is toxic to many cytosolic enzymes (page 2, line 28). In contrast, many cellular enzymes are activated by K^+, which is the most abundant cation in the cytoplasm (page 2, lines 28-30). Certain cytoplasmic

enzymes arc especially prone to Na^+ inhibition when K^+ concentration is reduced (page 2, lines 30-31). Therefore, maintaining intracellular K^+ and homeostasis to preserve a high K^+/Na^+ ratio is important for all cells and especially critical for plant cells (page 2, lines 31-32).

This problem disclosed by the Applicants manifests itself because of limited water supplies and the widespread use of irrigation, which have resulted in the increases salinity of the soils of many cultivated areas (page 3, lines 13-14). In particular, modern agricultural practices such as irrigation impart increasing salt concentrations when the available irrigation water evaporates and leaves previously dissolved salts behind (page 3, lines 14-16). Accordingly, there is a need to increase salt tolerance in plants, particularly those plants which are advantageously useful as agricultural crops (page 3, lines 30-31). As set forth in the specification at page 5, lines 15-17 and page 16, line 29 to page 18, line 27, Applicants detail the role played by the present inventive polynucleotides and proteins, which once again satisfies the "need only make one credible assertion" test set forth by the CCPA in Gaubert.

Based on the above-indicated asserted utilities and the Examiner's failure to refute each and every asserted utility, Applicants request withdrawal of this ground of rejection.

The rejection of Claims 5-8 under 35 U.S.C. § 112, first paragraph ("written description") is obviated by amendment.

The Office has alleged that the specification fails to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (paper number 10, page 8, lines 3-5). It appears that this ground of rejection is based on the absence of a "description of domains that are specific to this particular serine/threonine kinase nor domains that are important for its proper function." (paper number 10, page 8, lines 12-14). Applicants have amended Claims 5-8 to include a

recitation that the isolated polynucleotides within the scope of these claims encode a protein having serine/threonine kinase activity. The serine/threonine kinase activity and methods of screening for this activity is exemplified in the specification at page 12, line 18 to page 16, line 26.

MPEP § 2163.02:

> An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989).

Applicants submit that the specification provides an adequate description to allow the skilled artisan to recognize what has been invented and what is claimed is adequately described in the specification within the meaning of 35 U.S.C. § 112, first paragraph.

Accordingly, withdrawal of this ground of rejection is requested.

The rejection of Claims 1-22 and 32-35 under 35 U.S.C. § 112, first paragraph ("enablement") is obviated in part by amendment and traversed in part.

The Office has taken the position that the claimed invention is not supported by an enabling disclosure (paper number 10, page 9, line 6). Applicants respectfully disagree.

MPEP § 2164.04 states:

> In order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)

With respect to Claims 1-4, 9-22, and 32-33, Applicants note that the Examiner has not provided any reason and/or explanation for rejecting these claims as lacking enablement. Accordingly, the rejection of Claims 1-4, 9-22, and 32-33 under 35 U.S.C. §112, first paragraph, is not tenable and must be withdrawn.

Applicants note that, at page 11, line 7 to page 13, line 6 of paper number 10, the Examiner has stated his case with respect to the enablement of Claims 5-8. It appears that the Examiner has based this ground of rejection on the difficulties associated with predicting the activity of a protein encoded by a polynucleotide sequence that is 70% to 90% identical to or hybridizes to the sequence of SEQ ID NO:1 (paper number 10, page 11, lines 7-9). Applicants believe that this rejection is obviated by the amendment present herein, in which Claims 5-8 now recite that the polynucleotide encodes a protein having serine/threonine kinase activity.

MPEP § 2164.01 states:

> The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.

Applicants submit that determining what sequences fall within or without the scope of present Claims 5-8 would be readily apparent to the skilled artisan. At page 12, line 18 to page 16, line 26, Applicants provide a detailed example of how the skilled artisan may clone, express, and characterize any sequence variant to assess its standing with respect to the claimed invention. The Examiner has provided a rather nice account of some of the difficulties associated with predicting activity from sequence and structure. However, the this discourse further underscores the fact that the activity now recited in these claims provides sufficient direction with respect to the scope of these claims, as well as the importance of the disclosure of the present invention to provide the skilled artisan with express guidance to assess serine/threonine kinase activity.

In fact, MPEP §2164.06 states:

> ... quantity of experimentation needed to be performed by one skilled in the art is only one factor involved in determining whether "undue experimentation" is required to make and use the invention. "[A]n extended period of experimentation may not be undue if the

> skilled artisan is given sufficient direction or guidance." In re Colianni, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977). " 'The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.'

Applicants submit that, with the present specification in hand, determination of polynucleotide sequences that fall within the scope of Claims 5-8 would require nothing more than routine experimentation to determine sequence homology and protein activity. As such, Applicants submit that Claims 5-8 are fully enabled within the context of 35 U.S.C. §112, first paragraph.

Finally, the Examiner has outlined his perceived reasons for rejecting Claims 34-35, drawn to methods of increasing salt tolerance in a plant in need thereof, in paper number 10, page 10, line 1 to page 11, line 6. Much of the Examiner's argument centers on the physical interaction between SOS2 and SOS3; however, such a narrow view, further narrowed by the focus on other proteins that are outside of the scope of the present claims and may also interact with SOS3, is a misapplication of the test for enablement.

MPEP §2164.04 states:

> A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

At page 12, line 18 to page 16, line 9, Applicants provide a detailed explanation of how the skilled artisan may clone, express, and characterize the polynucleotides within the scope of Claims 34-35. Moreover, Applicants provide a detailed example on page 16, lines 10-26 of how to assess the up-regulation of expression due to salt stress.

The Office's allegation, that "just because the sos2 mutants exhibit an increased sensitivity to high Na^+ concentrations, does not mean that over-expressing SOS2 will automatically produce plants with an increased tolerance to Na^+" (paper number 10, page 11, lines 4-6), is of no moment. Applicants submit that it would be well within the purview of the skilled artisan to apply the latter method, described on page 16, lines 10-26, to assess increased salt tolerance based on SOS2 expression under many scenarios; including, but not limited to expression of SOS2 homologs, and increased expression of SOS2.

Moreover, MPEP §2164.05(a) states:

> The specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public... The state of the art existing at the filing date of the application is used to determine whether a particular disclosure is enabling as of the filing date.

The MPEP further states in §2164.02:

> The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation.

Therefore, the failure to state each any every possible method by which the proteins' activities are increased, in and of itself, is not sufficient to support an enablement rejection, nor is the omission of a working example.

Based on the foregoing, Applicants submit that the present claims are fully enabled by the specification and the common knowledge available in the art and as such withdrawal of this ground of rejection is requested.

The rejection of Claims 4-8, 34, and 35 under 35 U.S.C. §112, second paragraph, is obviated in part by amendment and traversed in part.

The Examiner has rejected Claims 34 and 35 based on the terms "increasing" and "in need thereof." Applicants submit that these terms are appropriate and definite within the context of 35 U.S.C. §112, second paragraph.

The CAFC has recently ruled in a case having similar claim language as the present application (See the attached copy of Rapoport v. Dement, 59 USPQ2d 1215 (CAFC 2001)). In Rapoport, the Court determined that a method for the treatment of sleep apneas fails to include the treatment of anxiety because the method of treatment of sleep apneas requires the identification of "a patient in need of such treatment" (see page 7, lines 30-34; page 8, line 36 to page 9, line 1; and page 9, lines 26-28, of Rapoport). The Court explained that the basis of its decision relied on the fact that the phrase "treatment of sleep apneas" was included "as a claim limitation" because "the phrase 'to a patient in need of such treatment' would not have proper antecedent basis" otherwise (see page 7, lines 30-34, of Rapoport). Therefore, according to the Rapoport Court one must identify a "patient in need of such treatment" in order to treat the underlying phenomena.

Like Rapoport, the present invention relates to a method, which contains the identification of "a plant in need thereof." Therefore, the identification of a population of plants in need of increasing salt tolerance is also included in this presently claimed method (i.e., it is an inherent selection step).

Moreover, Applicants submit that the phrase "increasing the salt tolerance" should appropriately be treated as the underlying phenomenological event, which is the object of this selection step. Furthermore, Applicants submit that the skilled artisan would readily appreciate that the phrase "A method of increasing the salt tolerance of a plant in need thereof" would have an inherent comparative basis: increased with respect to the same plant prior to the claimed method.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection of Claims 4-8, 34, and 35 under 35 U.S.C. §112, second paragraph.

The rejection of Claim 4 under 35 U.S.C. §102 over Boudet et al is obviated by amendment. Withdrawal of this ground of objection is requested.

Regarding the objection to the drawings, Applicants submit herewith drawings corrected in accordance with form PTO-948. Withdrawal of this ground of objection is requested.

The objections to the specification and of Claims 33 and 35 are obviated by amendment. Withdrawal of these grounds of objection is requested.

With respect to the Information Disclosure Statement filed on August 17, 2001, Applicants respectfully request additional information. In paper number 10, page 3, numbered paragraph 5, the Examiner indicates that the Information Disclosure Statement fails to comply with 37 C.F.R. §1.98(a)(1). Applicants note that 37 C.F.R. §1.98(a)(1) simply requires that: "Any information disclosure statement filed under §1.97 shall include: a list of all patents, publications, applications, or other information submitted for consideration by the Office." Applicants submit that the Information Disclosure Statement filed on August 17, 2001 is fully compliant with this provision of the Code of Federal Regulations. In particular, Applicants note that along with the Information Disclosure Statement a "List of Related Cases" was filed. Accordingly, Applicants request that the Examiner provide a detailed explanation of the basis for objection to ensure that the Information Disclosure Statement is considered.

Applicants submit that the application is in condition for allowance. Early notice to this effect is earnestly solicited.

Respectfully submitted,

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